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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,218	09/08/2003	Ernst Peter Strecker	12013/56004	1060
23838	7590	01/11/2006	EXAMINER	
KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004			WILLSE, DAVID H	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 01/11/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/656,218	<b>Applicant(s)</b> STRECKER, ERNST PETER	
	<b>Examiner</b> Dave Willse	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 33-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on September 8, 2003, is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 08/087,520.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9-8-03</u> . | 6) <input type="checkbox"/> Other: _____  |

The disclosure is objected to because of the following informalities: At the beginning of the specification, the patent number corresponding to U.S. application serial number 09/776,850 should be included. In the replacement paragraph at page 16, lines 1-21, of the Preliminary Amendment of September 8, 2003, reference characters "12", "13", and "18" should apparently be replaced by --42--, --43--, and --48--, respectively. In claim 42, line 2, "longitudinal" is misspelled. Appropriate correction is required.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the wrinkled lining (claim 33, last three lines) must be shown or the feature canceled from the claim. No new matter should be entered. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Regarding claims 33-38, the disclosure as originally filed describes an embodiment having a wrinkled lining (e.g., US 6,193,746 B1: column 2, lines 21-38) but says nothing about said embodiment including a continuous and connected lining (claim 33, line 8), an inner lining portion (claim 34), a biodegradable lining (claim 35), a lining with several layers (claims 36 and 37), or a porous lining (claim 38). Likewise, there is no disclosed *structure* (as opposed to a lining) which defines three fluid orifices that expand when the structure is expanded (claim 39, lines 4-7). Various further limitations in dependent claims 40-48 are also absent in the original disclosure. Inherency may not be established by probabilities or possibilities (MPEP § 2163); when an explicit limitation in a claim “is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description *requires* that limitation” (*Hyatt v. Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998); emphasis added). The Preliminary Amendment of September 8, 2003, is not viewed as part of the original disclosure of the present application because the executed oath or declaration under 37 CFR 1.63 does not make reference to said Amendment. If the Applicant opts to change the present application to a continuation-in-

part, then the Applicant must follow the procedures set forth in MPEP §§ 201.11 *and* 714.01(e), section II. Said Amendment currently fails to comply with MPEP § 714.02 because the remarks do not specifically point out the support for added claims 33-48 in ancestor application serial no. 08/087,520. In view of Office policy for interpreting such claims (MPEP § 2163.06), other prior art may be applicable upon amending to overcome the aforementioned problems.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. When read in light of the specification, “the structure defining a first fluid orifice, a second fluid orifice, and a third fluid orifice” (claim 39, lines 4-5), along with other language, is misleading and confusing as to the scope of the claims, for reasons presented above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 33-38 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Schwartz, US 5,957,971. The embodiment shown in Figure 2 includes an elongated hollow structure 34 and a wrinkled lining 32 interfaced with a medication for delivery to a patient (column 5, lines 31-40; column 2, lines 24-27; column 4, line 30 et seq.). Regarding claim 34,

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the lining is positioned *within* the structure in the sense that it lies *between* successive helical coils of the stent 34 (Figures 2 and 10). Regarding claim 35: column 2, lines 28-29; column 6, lines 46-48; etc. Regarding claim 36: column 3, lines 40-43 and 65-67. Regarding claim 37, more than one medication would have been inherent from column 1, lines 51-55; column 2, lines 9-11 and 29-33; column 4, lines 15-17; column 6, lines 33-37; etc. Regarding claim 38, pores would have been inherent from the incorporation of controlled-rate microcapsules (column 4, lines 48-55).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



**Dave Willse**  
**Primary Examiner**  
**Art Unit 3738**